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Via overnight delivery, email and EPA's electronic docket

Mr. John W. Pates, Jr.
Special Review and Reregistration Division
Office of Pesticide Programs
7508C
United States Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Dear John:

Re: Comments on EPA's document "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach"

Syngenta wishes to submit comments pertaining to the EPA's document currently open for public comment: "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach." The comments we are submitting are based upon a review of that document, which is also known as the EPA's "Preliminary/Comparative Risk Assessment" document (thereby referred to as the "PRA"), by Syngenta's scientists. For ease of the agency's review, the comments in the attachment are listed in sequential order (i.e. by PRA page number).

Syngenta's comments fall into four main categories or areas that we feel best represent the major deficiencies in the PRA document as released:

1) The EPA document is inaccurately titled and is presented as a "risk" assessment. However, it is evident that it should instead be characterized as a "hazard" assessment due to the magnitudes and probabilities that have not been assigned to adverse effects and to the lack of a benefit analysis (See attachment, comments 1, 3, 5, and 10);

2) The EPA document creates datasets from dissimilar data that cannot be directly compared, or from which simplistic conclusions of risk or hazard cannot be drawn (See attachment, comments 2, 4, 7, 8, 12, 16, 17, 18);

3) There is a bias against brodifacoum and for the supposed risk it represents throughout the document based upon supposition, selective use of data, and misleading representations of registered commensal rodenticide product labels and use patterns (see attachment, comments 3, 6, 9, 11, and 13); and

4) Wrong methodologies were utilized to yield some numerical values used in the assessment. Statements on data omissions and conclusions on data needs are largely unsupported (See attachment, comments 14, 15, and 20).

In addition to the Syngenta-specific responses noted above, Syngenta also agrees with the responses submitted to the agency by the Rodenticide Registrant Task Force (RRTF). The combined responses of this document and that of the RRTF represent a more complete response to the Agencies PRA.

Syngenta does not believe the PRA provides any new interpretation of non-target risk with regard to these well-studied and useful products. Further, without a properly prepared and quantified risk assessment, the document does little to assist registrants in designing research to elucidate rodenticidal product risk or to clearly indicate problem areas for the implementation of corresponding mitigation measures.

Syngenta believes that the agency should reconsider this flawed document for the aforementioned reasons. Syngenta desires to work with the Agency and other rodenticide registrants to initiate a meaningful assessment/studies that can best indicate the extent of risk presented by these rodenticides, and which can then lead to specific changes or improvements in these products and their use patterns. It is important to note that this process has already been initiated and that it would be in the agency's, the registrants' and the public's best interest to have a sound assessment done on these products.

Please call me at (336) 632-7096 if you have any questions about our response to this document.

Sincerely,

John L. Hott
Regulatory Product Manager

Enclosure: Attachment - Responses to the PRA

1. General error – No benefits analysis. This assessment appears to be more like a hazard assessment in a reduced risk rationale than a comparative risk assessment. As such, it should contain a comparative benefits analysis as well as a comparative "risk" analysis. It is important to note, for example, that the reason that second-generation anticoagulants were developed was to deter the resistance issues inherent in the first-generation rodenticides.

2. Page (i), ppg 2. "The available information from laboratory and pen studies…indicates a variety of potential avian and mammalian predators and scavengers are potentially at risk…"
The information used by the Agency for this statement is based upon studies with widely differing methodologies or observations and results and these data cannot be grouped or directly compared toward any kind of collective statement of this type.

3. Page (i), ppg 2. "A major concern in using rodenticides is that they are not selective to the target species…" This preliminary and basic argument of the PRA is flawed. The statement is correct if reference is made to toxicity. But by stating the word "using", the Agency is making the argument that labeled use directions for rodenticidal products does nothing to affect risk. When homeowners or applicators are using rodenticides according to label directions, they are placing them in inaccessible areas in and around structures, or in tamper-resistant bait stations. This Agency-registered use pattern for commensal rodenticides greatly limits risk and therefore selectivity of these products.

4. Page (ii), 4th bullet. "Information from 258 incident reports indicates that birds and non-target mammals are being exposed. By both primary and secondary routes of exposure". The incident report data is principally based upon carcass autopsies and thus cannot determine the route of exposure. It is unknown.

5. Page 1 - Error in the title. The title is flawed since the EPA document is a comparative "hazard" not "risk" assessment of nine rodenticides to birds and nontarget mammals. In his book *Ecological Risk Assessment* (1993), Glenn Suter defines risk assessment as, "*the process of assigning magnitudes and probabilities to the adverse effects of human activities or natural catastrophes.*" Clearly, EPA has not assigned magnitudes and probabilities to adverse effects. EPA's own guidance document (EPA, 1998) The title should be changed to, "Potential Hazard of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach." Also, most if not all uses of the word "risk" in this document should be replaced with "hazard".

6. Page 1, ppg 1. "…"In and around buildings" may be interpreted differently among rodenticide users". The Agency feels the differences between agricultural and commensal rodenticide uses are vague because of the 'in and around' statement. This is not the only use direction on commensal rodenticide labels! It also states to apply where rodents are active (examples given), and to place bait in inaccessible areas or in tamper-resistant bait stations.

7. Page 4, ppg 3. "Some LD50 values…from the literature… are considered supplementary because…[test parameters} are not reported or may not meet Agency test guideline requirements." Here, the Agency accepts the fact that basic LD50 data cannot always be directly compared, yet elsewhere (e.g., page i, ppg 2) the Agency makes definitive statements from consolidating dissimilar or irrelevant data and information.

8. Page 6, 2nd full paragraph – Error in design of comparative assessment of multiple compounds with very different modes of action. EPA states that, "The methodology used in the comparative analysis model is similar to that used in the Agency's 'Comparative Analysis of Acute Risk From Granular Pesticides' (EPA 1992) and 'A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study' (EPA 1998d)." However, in both comparative analyses cited above, the modes of action were the same or similar. In the current assessment, the modes of action are very different between chemical classes. Therefore, the design of this comparative assessment is flawed. Trying to compare 9 different compounds with 4 different modes of action is an "apples and oranges" comparison. It is impossible to properly assess the risk of 9 compounds with 4 different modes of action. EPA admits on page 99-100, EPA that one of the factors which contributes uncertainty to their analysis is, "(7) comparing rodenticides with different modes of action, i.e., vitamin K antagonists that disrupt normal blood-clotting (anticoagulants), a diphenylamine that is a neurotoxicant, and inorganic compound that kills by liberating phosgene gas, and a sterol that kills by inducing hypercalcemia."

9. Page 8, last ppg. Here the Agency prefaces the tables to follow on acute oral LC50 and LD50 values without any summary or qualification. It should be noted that the avian LD50 values are lower for difethialone than for brodifacoum in table 4, page 14. Yet on Page 23, referencing the secondary hazard data, the Agency is quick to assign brodifacoum as having the greatest hazard "based upon available laboratory studies".

10. Page 9, 1st full paragraph – Error in assigning absolute risks without an exposure analysis. EPA states, "In preliminary pesticide assessments the assumption is made that nontarget birds and mammals are likely to be exposed to the pesticide without attempting to establish a quantitative measure of this likelihood." However, numerous tables and figures contain absolute "risk" values without a quantitative exposure analysis. Absolute "risk" values should not be assigned to

the rodenticides in this assessment without an accompanying exposure assessment.

11. Page 17, Table 6. Dog values incomplete. The Agency has been given other publications with more robust dog LD50 values but they insist upon only citing the 0.25 to 1 mg/kg figure which based upon a flawed preliminary ranging study that did not show a clear dose-response effect. The definitive value based upon a study with hundreds of adult dogs is 3.56 (2.13 – 6.03) mg/kg in Godfrey, M.E.R., "Acute oral toxicity of the anticoagulant brodifacoum to dogs", New Zealand J. of Expt. Agriculture, 9: 147-9, 1981.

12. Page 23 – Conclusions on secondary hazard studies with raptors. These conclusions cannot be made because the studies were of widely differing types, dose regimes, sample sizes, etc. There is no data reported on difethialone.

13. Page 58 – ppg 3 through page 59, ppg 2. These studies are irrelevant to a determination of the risk of commensal rodenticides in the USA. Totally different situation.

14. Page 61- Table 31. It is not appropriate to utilize the target species as the representative mammal to 'scale up' to 1 kg sized mammal. These anticoagulant molecules were selected based upon their toxicity to rodents. Another species such as canine or feline would be more representative of risk to non-target mammals. The diphacinone value and others would change drastically with just this change in how the table is constructed.

15. Page 74, ppg 1 on RQ – for secondary risks cannot be calculated because no LD50/LC50 data available. Harrier LD50 is in Table 3 (p 13), yet given even more values for other raptor species, does it follow that secondary risk could easily be determined with more LD/LC data available? There is still the issue of exposure, doses, interval of ingestions, metabolism, and other dynamics.

16. Page 74, ppg 2. Meaningless to cite percentage of total test subjects that died; they were subject to widely differing protocols and dosages

17. Page 76, ppg 1, page 77, ppg 2 through 4 – Information from field studies. These were not commensal rodent applications and any findings are irrelevant.

18. Page 76, last ppg, page 77, first ppg. Field studies or observations of barn owls in New Jersey (Hegdal, et al) are contrasted with those in Malaysia (Duckett). Barn owls in the USA can be considered as the most 'commensal' of raptors. However, the Hegdal study verified that these owls principally take voles and other smaller prey items. Norway rats (typically weighing 150-350 g) are too big a prey item for barn owls in the USA. Barn owls in Malaysia are much larger. When they coexist in habitats such as in the oil palm plantations that Duckett

studied with local populations of smaller rat species (R. rattus primarily), they will prey on the rats almost exclusively. Baiting oil palm plantations with rodenticides where owls are being maintained for rodent control (through the installation of next boxes) is lunacy on the part of local plantation managers, not a sign of risk for US applications.

19. Page 84, ppg 3. The Agency attempts to discredit the RRTF threshold theory with reference to toxicity in a possum. One could question why a mammal is being used when the issue is with birds? The screech owl study involved a broadcast application, non-commensal rodents, a different brodifacoum formulation and concentration of bait, and an orchard habitat.

20. Page 99-100 – Errors in uncertainty analysis and data needs. (1) (c) Is the Agency suggesting that additional toxicology studies should be done with predators and scavengers? Are not these the organisms the Agency is trying to protect? (3) Specific use information has already been provided to the Agency. Since the Agency has written a very conservative hazard assessment, it follows that the Agency could use labels to determine the worst-case exposure scenario in/on a given area (e.g., rodenticide placed every X feet around a pig farm and its associated structures). This type of assessment could be very important if it included both a spatial and temporal (i.e., reduction of baits to zero once rodent population is controlled) component. (7) See comment 3 above. There also is mention of avian reproduction studies, which, if done under current guidelines (i.e., continuous dietary exposure for 20 weeks), will provide data that cannot be used in a meaningful risk assessment and simply will be a waste of animals, time, and money.